K042379

DEC 15 2004

510(k) Summary

1) Submitter's Name Address, contact	BIOSAFE Laboratories, Inc. 100 Field Drive, Suite 240 Lake Forest, IL 60045 Phone: (847) 234-8111 FAX: (847) 234-8222	
	Contact Person:	Jack A. Maggiore, PhD BIOSAFE Laboratories, Inc. (773) 693-0400, x253
	Date Prepared:	August 19, 2004
2) Device Name	Proprietary Name:	*AnemiaPro™ Self-Screener*
	Common Name:	Device to determine **hemoglobin** concentration in capillary whole blood
	Classification Names:	Whole Blood Hemoglobin Assays (21 CFR 864.7500)
3) Predicate Devices	Cell Dyn 3700 Analyzer , Abbott Laboratories, Inc. HemoCue B-Hemoglobin Instrument, HemoCue, Inc.	
4) Device Description	The device is a kit containing the materials necessary to self-collect and test a capillary blood sample using a single-use, disposable unit. The test unit is a self-contained plastic housing for a nitrocellulose-based test strip, which employs the principals of blood cell separation. The plasma that is obtained during blood separation migrates through the test strip, and the migration front is made visible by staining with an impregnated dye. The plasma migration distance is linearly and inversely proportional to hemoglobin concentration. The kit is comprised of a blood testing unit packaged in a foil pouch, alcohol prep pad, disposable lancets, gauze pad, bandage strip, and collection instructions containing information about anemia..	
5) Intended Use	The *AnemiaPro™ Self-Screener* is intended for over-the-counter distribution, for the determination of hemoglobin concentration in a self-collected capillary whole blood sample. The device is not intended for use in neonates.	

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510(k) Summary, *continued*

6) Comparison to predicate device	The ***AnemiaPro™ Self-Screener*** has technological characteristics that are substantially equivalent to that of the predicate devices listed above. The ***AnemiaPro™ Self-Screener*** provides components that permit self-collection and testing of a capillary blood sample for determination of hemoglobin Results of clinical trials have shown that self-collected capillary samples correlate closely with paired venous whole blood samples tested with the aforementioned predicate devices.
7) Performance Studies	Performance studies were conducted on self-collected capillary blood samples from volunteer study subjects at three different geographical trial sites. A corresponding venous blood sample and a professionally collected capillary blood sample were collected by the health care professional in order to compare venous hemoglobin results to those obtained from both capillary blood samples tested on the Anemia Test Devices. Venous samples were express shipped to BIOSAFE Laboratories for hemoglobin analysis using the predicate methods.
8) Test Summary	Performance characteristics studied included precision, linearity, analytical accuracy and correlation. In addition, the *AnemiaPro™ Self-Screener* was evaluated for effects of interferences and sample environmental factors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Jack A. Maggiore, Ph.D.
President, Chief Scientific Officer
BIOSAFE Laboratories, Inc.
8600 W. Catalpa
Chicago, Illinois 60656

DEC 15 2004

Re: k042379
Trade/Device Name: AnemiaPro™ Self-Screener
Regulation Number: 21 CFR § 864.7500
Regulation Name: Whole Blood Hemoglobin Assays
Regulatory Class: II
Product Code: KHG, GIG
Dated: November 8, 2004
Received: November 12, 2004

Dear Dr. Maggiore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042379

Device Name: AnemiaPro™ Self-Screener

Indications For Use: The *AnemiaPro™ Self-Screener* is intended for over-the-counter distribution, for the determination of hemoglobin concentration in a self-collected capillary whole blood sample. The device is not intended for use in neonates.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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